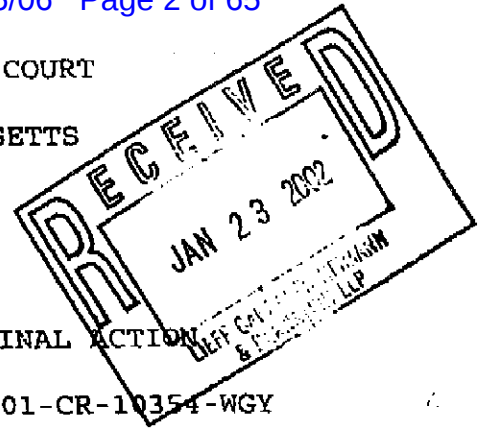


# EXHIBIT B

Lupron Settlement

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
EASTERN DIVISION



UNITED STATES OF AMERICA :

v. :

TAP PHARMACEUTICAL PRODUCTS, INC.:

CRIMINAL ACTION  
NO. 01-CR-10354-WGY

SENTENCING MEMORANDUM OF THE UNITED STATES

Comes now the United States of America, by Michael J. Sullivan, United States Attorney, and Michael K. Loucks, Health Care Fraud Chief, and Susan G. Winkler, Assistant United States Attorney for the District of Massachusetts, and files this Sentencing Memorandum in support of the Rule 11(e)(1)(C) plea agreement and sentence, and the attendant global settlement agreement entered into between the United States Attorney in this District, the United States Department of Justice, prosecutors in all fifty states and the District of Columbia, and the Office of General Counsel for the Department of Health and Human Services, on the one hand, and the defendant TAP Pharmaceutical Products Inc., on the other hand.

TAP and the Government have reached a global criminal and civil settlement agreement resolving all of TAP's criminal and civil liability regarding the marketing and sale of the drugs Lupron and Prevacid. The broad terms of that agreement are described in the first section of this memorandum. Now before

the United States District Court for review is the proposed Rule 11(e) (1) (C) plea agreement and whether that agreement fairly and adequately punishes TAP for its criminal conduct and provides restitution to victims of that conduct.

TAP has been charged with and has pled guilty to violation of 18 U.S.C. section 371, conspiracy to violate Title 21 United States Code sections 333(b) and 331(T) by causing the sale of drug samples. Set forth in this memorandum is a brief description of the criminal conduct, followed by an analysis of the estimated loss caused by TAP and the other members of the conspiracy to patients and their insurers, principally the federal and state health care programs. The conduct of TAP and its employees presents a corporate wide scheme to induce physicians to purchase TAP's drug Lupron by providing free samples of the product to physicians, with the intent and expectation that those individuals would use and bill those free samples to their patients and their insurance companies.

The charged criminal plan was a conspiracy to provide free samples to physicians and other customers to induce them to prescribe lupron to patients suffering from prostate cancer. In addition to free samples as inducements, TAP also provided other forms of inducements to customers, including off-invoice price discounts, all expenses paid trips, "educational grants", payment of bar tabs, payment of holiday party expenses, financial support

for advertising expenses, free consulting services, and forgiveness of debt. Provision of these non-free product inducements are not charged in the instant Criminal Information. In evaluating the losses caused by the conspiracy, the United States Attorney's Office was cognizant of, and took into account, estimates of those additional losses to insure that the global criminal and civil settlement: fully and fairly punishes TAP for all of its criminal conduct, including other relevant criminal conduct not charged in the criminal information, as provided for in U.S.S.G. section 1B1.3; and fully and fairly compensates the affected federal and state health care programs for their losses. In addition, the proposed global criminal and civil settlement agreement necessarily contemplates TAP's continued participation as a provider of drugs to various federal and state health care programs; integral aspects of the proposed agreement are a stringent and sweeping Corporate Integrity Agreement and agreements between TAP and all fifty states and the District of Columbia, which agreements impose numerous restrictions upon TAP's corporate "freedom" and regulate the manner of future drug price reporting by TAP.

The proposed settlement does not include any monies for any private insurance companies or patients who may also have suffered losses. Inclusion of such damages would unduly complicate and prolong the sentencing proceeding in this case.

This is explained and demonstrated more fully below. In addition, some patients and health insurers have commenced litigation against TAP to recover overpayments caused by the criminal conduct and thus have a forum in which to demonstrate and obtain any appropriate damages.

I. Proposed Criminal and Civil Resolution

The proposed civil and criminal resolution in this matter is the product of a more than four year investigation and approximately two years of negotiations between the United States Attorney's Office in this District and TAP. The agreement includes: the plea agreement in this case setting forth TAP's punishment for its criminal conduct; a civil settlement agreement between TAP and the United States, resolving TAP's civil fraud exposure to the Medicare, Medicaid and other federal programs; a Corporate Integrity Agreement with the Office of Inspector General, Department of Health and Human Services, governing TAP's future conduct as a provider of pharmaceutical products to beneficiaries of the various federal and state health care programs; and an agreement with all fifty states and the District of Columbia concerning TAP's financial and marketing responsibilities to the State Medicaid Programs.

In summary:

- (a) TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act and to pay a \$290,000,000 criminal fine, the largest

criminal fine ever in a health care fraud prosecution. The Plea Agreement between the United States and TAP specifically states that TAP's criminal conduct caused losses of \$145,000,000.

- (b) TAP agreed to settle its federal civil False Claims Act liabilities and to pay the United States Government \$559,483,560 in civil damages for losses suffered by the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct.
- (c) TAP agreed to settle its civil liabilities to the fifty states and the District of Columbia in an amount of \$25,516,440 for losses the states suffered both from TAP's drug pricing and marketing misconduct, and from TAP's failure to provide the state Medicaid programs its best price for those drugs as required by law.
- (d) TAP agreed to comply with the terms of a corporate compliance program which, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff, and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs.

Given that the agreement requires TAP to pay simple interest on all of the civil sums at the rate of 6% per annum commencing on September 4, 2001, the total to be paid by TAP on Friday, December 7, 2001 if the Court approves the Rule 11(e)(1)(C) plea agreement on Thursday December 6 will be \$875,000,000, plus interest of \$9,039,451.72, for a grand total of 884,693,629.32, or almost nine hundred million dollars.

## II. The Law

The Prescription Drug Marketing Act provides in pertinent part as follows:

Title 21 United States Code section 331(t) prohibits the sale, purchase and trade, and the offer to sell, purchase and trade, drug samples in violation of section 353(c) of that Act. Section 331(t) also prohibits causing such conduct.

Section 353(c) provides that no person may sell, purchase or trade or offer to sell, purchase or trade any drug sample. Section 353(c) applies to samples of a drug which are intended for human use but, because of toxicity, potential for harmful effect and method of use, and the collateral measure necessary for use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drug and with written prescription of such practitioner. Section 353(c)(1) further provides that a sample of such a drug is a unit of drug not intended to be sold but intended to promote the sale of the drug. The drug Lupron, sold by TAP, is a drug subject to the requirements of Section 353(c)(1) and any free samples of the drug Lupron provided to physicians by TAP sales representatives, as set forth in this Indictment, were drug samples within the meaning of Section 353(c)(1).

Section 353(c)(3) permits a manufacturer of a drug to distribute samples of the drug through its sales representatives

but only if a practitioner licensed to prescribe the drug made a written request for such samples, which request contained at least the following: the name, address and professional designation of the practitioner, the identity and quantity of the drug requested, the name of the manufacturer of the drug, the date of the request, and the practitioner's signature.

18 U.S.C. section 371 makes it a crime to conspire with others to commit an offense, and if, thereafter, one of the conspirators commits an overt act in furtherance of the conspiracy.

### III. Relevant Facts

#### A. Sources of Evidence

In evaluating losses suffered by TAP's criminal conduct, the United States has collected and used the following information:

- (1) Evidence from TAP, including an electronic database that reflects all invoices for sales in the 1990s (to the extent that that information had been collected by TAP and preserved in its database) and the distribution of all drug product sold on an invoice that reflected a unit sales price of \$0;
- (2) An electronic database from a company (referred to as Epsilon in this memorandum) employed by TAP to monitor and track distribution of samples as reported to that company by TAP's sales representatives;
- (3) Portions of an electronic database from the Medicare Program containing records regarding



billings by urologists for Lupron and Zoladex; and

- (4) Billing records for selected urologists for Lupron and Zoladex prescribed to patients.

In addition, the Government has evaluated a substantial number of documents provided by TAP and others in response to subpoenas (in excess of 500 boxes).

B. TAP

TAP Pharmaceuticals, Inc., is a joint venture equally owned by Abbott Laboratories and Takeda Chemical Industries Ltd., a Japanese company. Abbott Laboratories is publicly traded. Abbott provided to TAP certain corporate services/departments, including legal, packaging, invoicing, and auditing. Abbott and Takeda alternate in appointing the president of TAP for a fixed term. During the 1990s, TAP had two principal products, Lupron and Prevacid.

C. The Drugs Lupron, Zoladex and Prostate Cancer

The drug Lupron is a GnRH agonist and is used in the treatment of patients suffering from prostate cancer. As a general medical matter, the hormone testosterone, naturally produced by men, promotes the growth and spread of prostate cancer. One treatment for advanced stage prostate cancer has been the suppression or elimination of testosterone in men suffering from that disease. Testosterone can be eliminated through the removal of the testicles by a surgical procedure

called an orchiectomy. Alternatively, men's production of testosterone can be chemically suppressed through the administration of a GnRH agonist like Lupron. Patients whose prostate cancer is treated with a GnRH agonist typically receive regular injections of the drug for the remainder of their lives. Most men suffering from prostate cancer and receiving Lupron injections are over the age of 65 and have as their primary insurer the Medicare program.

TAP received approval from the Food and Drug Administration to sell Lupron for the treatment of advanced stage prostate cancer in the 1980s; the FDA approved the one month form of the drug in 1989, and the three month version in 1995. A four month version was approved in 1997. Lupron is administered in liquid form to patients by intramuscular injection, typically in the buttocks or arm, by a physician or by a nurse under the supervision of a physician.

TAP also had approval from the Food and Drug Administration to sell Lupron for the purpose of treating endometriosis and fibroids in women. The most common dose form for this purpose was known as "Lupron 3.75 mg." Women treated for endometriosis are typically of child bearing years and not insured by the Medicare program, but many are insured by the State Medicaid programs.

Throughout most of the 1990s there was a competing drug

called Zoladex. Zoladex was administered in solid pellet form by injection under the skin of the patient's abdomen, by a physician or by a nurse under the supervision of a physician. At various times in the 1990s, Zoladex was available in one month and three month doses.

While having different methods of administration, Lupron and Zoladex are essentially identical in medical efficacy in the treatment of prostate cancer. Throughout the 1990s, and as regards the treatment of men suffering from advanced stage prostate cancer with a GnRH agonist: some doctors prescribed only Lupron; some doctors prescribed only Zoladex; some doctors prescribed Lupron to some patients and Zoladex to other patients; some doctors alternated prescription of those two drugs, sometimes on a monthly basis, to the same patient; and some doctors abruptly switched every patient in their medical practice from monthly or quarterly administration of one of the two drugs to the other.

D. Medicare and Coverage

The Medicare Program as a general matter does not cover the cost of prescription pharmaceuticals which a Medicare Program beneficiary obtains pursuant to a prescription and thereafter self administers (i.e., by swallowing the drug in liquid or pill form). Among other reasons, because Lupron and Zoladex are administered by injection, the cost of both drugs were covered

Medicare benefits.

Most patients suffering from prostate cancer -- more than seventy-five percent -- are insured through the Medicare program and most of those patients -- more than 85% -- have supplemental insurance to cover the cost of the copayment for a drug like Lupron or Zoladex. A small percentage of patients suffering from prostate cancer have no insurance coverage at all.

Prior to January 1, 1992 and the implementation of 42 C.F.R. section 405.517, Medicare paid for injectable pharmaceuticals, including Lupron, based upon the average wholesale prices for those drugs as published from time to time in a pharmaceutical industry publication known as the "Redbook." 42 C.F.R. section 405.517, which became effective on or about January 1, 1992 required the Medicare Program to reimburse physicians for injections of Lupron and Zoladex at an amount equal to the lower of the physician's "estimated acquisition cost" or the "national average wholesale price" ("AWP") for each drug. That regulation allowed the Medicare program and its carriers to determine the estimated acquisition cost for a drug "based on surveys of the actual invoice prices paid for the drug" and to consider "factors such as inventory, waste and spoilage."

From January 1, 1992 through May 1997 in all fifty states, upon receipt of a claim form from a physician for the

administration of Lupron, the Medicare carrier in the particular state paid to the physician 80% of the billed charge contained on the Medicare claim form or 80% of the published national average wholesale price for the drug, whichever was less. The physician was responsible for billing the patient or the patient's supplemental insurer for the remaining 20%. After May 1997, the Medicare Program in some states began to employ a least costly alternative payment policy, which is described below.

The Redbook has published average wholesale prices for the various doses of Lupron and Zoladex, as well as for many other drugs. The Redbook, in periodically announcing the average wholesale price for Lupron, simply published those prices for Lupron that TAP had previously supplied to the Redbook, and those prices for Zoladex that its manufacturer had supplied. TAP knew that TAP could "raise" the average wholesale price of Lupron at any time by simply forwarding to the Redbook a new and higher average wholesale price. This allowed TAP, in effect, to control the maximum Medicare reimbursement paid to a doctor for prescription of Lupron: TAP could increase the maximum reimbursement that Medicare paid to physicians for an injection of Lupron simply by forwarding a new, higher average wholesale price for Lupron to the Redbook.

In Table 1 below, the second column reflects the published

Redbook AWP for Lupron from 1993 through 1999. If a doctor billed that amount to Medicare in every state from 1993 through May 1997, Medicare paid the amount in the third column; 80% of the billed charge (if the doctor billed less, he received 80% of that lesser amount; if he billed more than the AWP, he received only 80% of the published AWP). In certain states after May 1997, the doctor received only 80% of the published AWP for Zoladex (see Table 5). The fourth column reflects TAP's average sales price to all physicians nationwide.

TABLE 1			
Date	AWP as Listed in the Redbook	Medicare Payment if Physician Billed AWP	TAP's Average Sales Price To Physicians
1993	\$437.50	\$350.00	\$340
1994	463.75	371.00	346
1995	477.50	382.00	350
1996	496.25	397.00	356
1997	515.63	412.24	329
1998	540.63	432.50	222
1999	594.65	475.72	207

The steep drop in average sales prices to physicians beginning in 1997 was in part caused by the implementation of least costly alternative ("LCA") reimbursement, described below: that change in reimbursement by some Medicare carriers in some states drove

down the price that TAP could charge physicians in those states.

1. Profits from Prescribing Lupron and the Initial Free Drug Program

As reflected in the Table 1, throughout the 1990s, TAP routinely charged physicians who bought Lupron from TAP substantially less than the published average wholesale price for Lupron. Because TAP charged the urologist less than the published average wholesale price for Lupron, a physician could earn a profit by choosing to treat a patient's prostate cancer with Lupron, provided that the physician billed the patient's insurer, including the Medicare Program, at the published Redbook price for Lupron and also thereafter billed the copayment to the patient. TAP called this profit or spread "Return to Practice." In or about 1991, TAP established this "Return to Practice" by setting its list price for Lupron at 80% of the published Redbook price, to insure that a physician would earn at least a 20% profit from the prescription of the drug, so long as the physician billed Medicare at the published price and collected the copayment from the patient.

Using Table 1, a doctor who purchased a one month injection of Lupron from TAP in 1995 at TAP's average sales price to physicians of \$350 and thereafter billed that injection to Medicare at the published AWP of \$477.50 collected from Medicare \$382. If the doctor did not bill or collect any copayment from

the patient and/or the patient's supplemental insurer, the doctor earned a \$32 profit from the prescription of that one dose. If the doctor collected the full copayment, his profit from the one injection was \$127.50. By 1996, his profit from the prescription of one injection of Lupron had increased to \$140.25. For a doctor with thirty patients in his practice receiving monthly injections of Lupron, the profit potential from prescribing Lupron was, in 1996, \$50,490.

Table 2 below sets forth for each drug for the years 1992 through 1999: the published AWP, each company's list price, and the Return to Practice spread or profit that could be earned from the prescription and administration of each drug, were the drug sold to the urologist at that list price and billed to the Medicare program at the published AWP.

TABLE 2						
Year	Lupron AWP	80% of Lupron AWP	RTP between AWP and List Price	Zoladex AWP	80% of Zoladex AWP	RTP Between AWP and List Price
1992	\$418.78 - \$437.50	\$335- 350	83.78- 87.50			
1993	\$451.25	\$361	\$90.25	\$318.75	\$255	\$63.75
1994	\$463.75	\$371	\$92.75	\$331.50	\$265.20	\$66.30
1995	\$477.50	\$382	\$95.50	\$358.55	\$286.84	\$71.71
1996	\$496.25	\$397	\$99.25	\$383.65	\$306.92	\$76.73



TABLE 2						
Year	Lupron AWP	80% of Lupron AWP	RTP between AWP and List Price	Zoladex AWP	80% of Zoladex AWP	RTP Between AWP and List Price
1997	\$515.63	\$412.50	\$103.13	\$410.51	\$328.40	\$82.11
1998	\$540.63	\$432.50	\$108.13	\$439.25	\$351.40	\$87.85
1999	\$594.65	\$475.72	\$118.93	\$469.99	\$375.99	\$94

To induce physicians to order Lupron in greater quantities, TAP and its management began in about 1991 to give free drug, as a form of quantity price discount, to physicians. In the early 1990s, the free-drug discount varied from physician to physician and included the following: one free injection for each five ordered, and one free injection for each ten ordered. When implemented, it was the expectation of TAP and its top management that physicians receiving the free drug would use and prescribe that free drug and would thereafter bill it to their patients and their insurers, including the Medicare program. In this early time period, TAP routinely provided more than 80 free one-month injections of Lupron to sales representatives for distribution to physicians.

## 2. The AUA Warning and TAP's Response

In about 1993, TAP and its top management were informed by a physician in a management position with the American Urology Association that urologists receiving free drug as volume

discounts were using and billing the free drug and that TAP was accordingly putting urologists at risk of criminal prosecution. That physician asked TAP to stop providing free drug to urologists. TAP's management, after meeting and considering the issue and its impact on their marketing of Lupron, determined to reduce, but not to eliminate, the free drug volume discount program, and determined to offer additional financial inducements to physicians through volume price discounts.

It is not clear to the Government that TAP in fact heeded this warning or modified the behavior of its employees. There is evidence that TAP in fact did slow down the distribution of samples briefly in 1993-1994, but by 1995, provision of samples had returned to their former levels. Table 4 below reflects the number of samples that sales representatives were reporting they had given to doctors. In 1993, that number stood at 11,271; in 1994, the first full year after the AUA warning, representatives reported giving doctors only 7,048 one-month injections. In 1995, that number had climbed back to 9,424 and by 1996, the reported number stood at 10,422.

Medicare reimbursement for Lupron in 1991 was only \$73 million. Table 7. By 1994, however, Medicare Program reimbursements for the prescription of Lupron had quadrupled to about \$295 million, and payment for Zoladex had increased to about \$36 million. By that point, the Medicare Program, through

its carriers, had not undertaken to conduct a survey of the actual invoice costs to physician's for either Lupron or Zoladex. Because of the increases in payments from 1991 to 1994 for injectable drugs as a whole, the Medicare program, through some of its carriers, attempted to obtain from physicians their actual invoice prices for Lupron and several other injectable oncology drugs in order to determine an estimated acquisition cost for each drug, as permitted by Section 405.517. TAP and its management were aware of and monitored these efforts.

In 1994, the American Society of Clinical Oncologists challenged this survey pursuant to the terms of the Paperwork Reduction Act. As a result of that challenge, and a statement by the General Accounting Office, the Medicare Program ceased any effort to survey physicians for invoice information. TAP and its management was aware of the challenge to the survey and HCFA's subsequent abandonment.

By August, 1994, and notwithstanding the warning to TAP's management from the AUA, the number of free samples provided to sales representatives had increased nationwide back to 80 samples per representative. In that month, a national account manager informed top management at TAP that sales representatives in California were providing free samples to physicians contingent upon sales (i.e., "if you order Lupron I will give you free samples") and in order to effect a lower than invoice price and

that this conduct put TAP at risk. Notwithstanding this second warning, this time from within, TAP did not undertake to control the free sample usage by sales representatives.

3. Free Drug and Physicians: the Numbers Provided

a. Available Free "Samples"

Table 3 below reflects the number of free samples that sales representatives had available to them to provide to physicians from 1993-1999. No data exists regarding the number of free samples TAP provided to its sales force in 1991 and 1992. In those years, when TAP was struggling to break into the market and to convince urologists that pharmaceutical treatment for prostate cancer was better than surgical treatment, one of TAP's marketing pitches concerned the amount of money that the urologist could make over the long term from drug treatment and how that exceed the dollars that the doctor could earn from surgery. The Government's evidence suggests quite strongly that providing doctors with free samples as volume discounts was an integral part of this sales effort. It is at least likely that the samples available to representatives in those years matched the samples available in 1993; it is also quite likely that in those two years TAP made many more samples available to the sales force in its initial effort to push its drug.

Numerous TAP sales employees have told the Government that from at least 1993, they routinely received 20 one month samples

each quarter or 80 each year to use at their discretion in selling Lupron. Throughout the 1990s the TAP sales force for selling Lupron stood at about 200.<sup>1</sup> The chart below reflects the dollar value of Lupron samples given by management to sales representatives, assuming the value of each one month unit to be the published average wholesale price. TAP sales employees have also told the Government that if they needed more samples to get or keep business, that they could get such samples by going through their district manager.

TABLE 3				
Date	Published AWP	Sales Reps	Samples provided	Value if billed at AWP
1993	\$437.50	220	80	\$7,700,000
1994	463.75	245	80	9,089,500
1995	477.50	245	80	9,359,000
1996	496.25	247	80	9,805,900
1997	515.63	193	80	7,961,327
1998	540.63	193	80	8,347,327
1999	594.65	193	80	9,181,396
Totals		1536	560	\$61,444,450

<sup>1</sup>The chart reflects the actual size of the Lupron sales force in 1994, 1997, 1998 and 1999. The government has estimated the 1993 number as slightly smaller than the 1994 number, and has estimated the 1995 number to be identical to the 1994 number. The 1996 number is based upon documents reflecting samples provided by sales representatives in the first quarter of 1996.

If every sales representative received the allotment of 80 per year and if every representative handed out every sample -- something that did not happen -- and if in 1991 and 1992 the value of samples was at least the average over the other seven years, TAP provided to its representatives had more than \$78,000,000 in free product to use to promote sales. There is in fact no way to determine how many of these available samples were actually given to doctors and, once provided, were billed by doctors to their patients and their insurers (or to which patients and to which insurers).

b. "Reported" Free Samples

As noted above, sales representatives were supposed to report their use of their available samples. According to the Epsilon electronic database, TAP representatives reported handing out in the years listed the samples indicated:

TABLE 4		
Year	Total Samples	Value if Billed at AWP
1993	11,271	\$4,931,062
1994	7,048	3,268,510
1995	9,424	4,499,960
1996	10,422	5,171,917
1997	11,496	5,927,682
1998	10,091	5,455,497
1999	3,654	2,172,778

Total	63,406	\$31,427,406
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The last column in the chart reflects the value of these samples if billed at the published AWP for Lupron. Note that the value of the reported samples is less than half the value of the available samples. It is and has always been the government's best estimate that the value of the samples actually provided by sales representatives to their customers falls somewhere between the two numbers. Note that in both of these two charts, the figures for the years 1997 through 1999 overstate the actual value of the samples because of the impact of the Least Costly Alternative reimbursement methodology employed by the Medicare carrier in many states in that time period. See discussion at III-D-4, below.

The Epsilon database understates the total number of free goods provided to a doctor. This is discussed more fully below at III-F-1.

c. Product Sold at a \$0 Unit Invoice Price

In addition to free samples, TAP also gave to doctors free product shipped with invoices that reflected a unit price of \$0. Such products were not tracked through TAP's free sample program and are accordingly not reflected in the Epsilon database; such product was also not a part of the sales representatives' quarterly allotment. The Government does not know how many free

drug were provided to urologists through this alternative mechanism, except to believe that the value of such product shipped on \$0 invoices is in the millions of dollars.

Two examples will suffice. According to the Epsilon database, Dr. X, identified below in Table 10, received 229 free samples that a sales representative documented by forwarding to Epsilon a sample signature card. TAP invoice records, however, reflect that Dr. X was also shipped 357 units of one-month Lupron on invoices that charged him a unit price of \$0. Thus, Dr. X received 586 free one-month injections of Lupron, more than 2.5 times the number reflected in the Epsilon database. Another doctor who, according to the Epsilon database, received only one free sample, appears in the TAP invoice database as receiving 224 products at \$0. Quite clearly, the free sample numbers listed above from the Epsilon database significantly understate the total volume of free product actually given to doctors and other customers.

These two doctors alone received 586 free product not through their sales representatives. The loss from this free product for just those two doctors, assuming all of the free drug was received and billed by them to their patients in 1996 at the 1996 AWP, was \$290,802. The Government cannot estimate with any precision the true magnitude of this "type" of free product. If just 10,000 extra free samples were provided to doctors



throughout the 1990s through this mechanism, and billed at an average AWP of \$500, the loss to patients and their insurers was more than \$5,000,000.

d. Poor Sample Accountability

TAP knew that its employees were not reporting accurately their handling of samples. Several audits conducted in the 1990s revealed deficiencies in sample accountability. Also, in 1995, one of TAP's sales executives institute a program designed to tie sample accountability to sales bonuses: if a representative had accounted for 100% of his sample allotment, then he/she would receive 100% of his or her earned bonus; as the sample accountability dropped below 100% the program similarly dropped the sales bonus. Top management at the company killed the program after only one quarter, given the outcry from the sales staff.

4. Volume Discounts and Least Costly Alternative Reimbursement

By 1995, TAP and the company selling Zoladex offered competing quantity discounts to urologists in an effort to provide a greater profit than the other company provided, as an inducement to the urologist to prescribe its product. One such example for 1995 is set forth in Table 5. TAP marketed to urologists these price discounts and the "return to practice" profits and urged urologists to bill the Medicare Program at the

published AWP and not to pass along any price discounts to the Medicare Program.

TABLE 5					
Lupron			Zoladex		
Quantity	Price	RTP/vial	Quantity	Price	RTP/vial
1-11	\$382	\$95.50	1-5	\$286.84	\$71.71
12-23	\$370.50	\$107.00	6-11	\$269.63	\$88.92
24-47	\$363.00	\$114.50	12-23	\$261.03	\$97.52
48-100	\$355.50	\$122.00	24-47	\$252.42	\$106.13
101+	\$344.00	\$133.50	48+	\$243.81	\$114.74

In one notable company sales promotion effort in the fall 1997, referred to within the company as the "Big Mac Attack" the sales force was trained in the sales of the four month Lupron and in how to deal with a growing phenomenon in the industry: the appearance of doctor buying groups. In these groups, doctors in different practices with small volume purchasing power would band together in a group to purchase Lupron (or Zoladex) in bulk, and thus obtain a larger discount from TAP (or Zeneca). Buying groups were a phenomena that TAP did not like, as the groups empowered individual physicians and had the effect of transferring some of TAP's profits to the physicians: the buying group did not affect the AWP paid by Medicare for Lupron, just the amount that TAP charged the physician. The training program

included presentations by top Sales management at TAP and included a slide presentation. One of the slides, regarding pricing strategy, contains the following:

What should I say to my physicians about contract confidentiality'.

Explain to physicians that discussing price could potentially put reimbursement in jeopardy

"Doctor by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCF then realized that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amount you may charge."

On the PowerPoint slide for the instructor, the following text appears:

The main point to make to physicians is that confidentiality clause is a protection for them. If word is leaked back to HCF/Medicare that the cost of Lupron is going down, they very well may take steps in reducing allowable. This tactic should help prevent physicians talking amongst themselves.

TAP's entire program of discounts - designed initially to replace the free product discount program - was premised upon the notion that doctors would not pass along any discounts they received in purchasing to patients and their insurers, including Medicare. The Government has concluded that, just as TAP and its employees did not expect physicians to pass along to their customers any price discounts, TAP and its employees also did not expect doctors to pass along any free drug "discounts" and fully

expected and intended doctors to bill patients for free drugs.

In 1996, the Medicare program paid more than \$450,000,000 for the prescription of Lupron. See Table 7. In that year, the published AWP for Lupron exceeded the published AWP for Zoladex by more than \$100 per one-month dose. Given that differential and the fact that the two drugs were medically efficaciously identical, the Medicare carrier in South Carolina implemented in 1996 a "least costly alternative", or "LCA" rule in reimbursement for claims for Lupron. That carrier announced that, commencing in January 1997, it would reimburse Lupron at the maximum allowed amount for the least costly alternative treatment, Zoladex. Actual implementation commenced in about May, 1997. As implemented, a physician who ordered a vial of Lupron from TAP received in South Carolina from Medicare 80% of the Zoladex AWP, or \$328.40, and from the patient or the supplemental insurance carrier, the remaining 20%, or \$82.10, for a total reimbursement of \$410.50. Because TAP's list price was then \$412.50, the physician purchasing Lupron the list price from TAP and prescribing Lupron to a patient could expect to lose \$2.00, absent a reduction in price from TAP or absent a volume discount. In contrast, a urologist choosing to prescribe Zoladex would continue to profit by at least \$82.11 per month per injection (see Table 2).

TAP and its management were aware of the South Carolina

carrier's implementation of LCA. Many urologists told TAP and its employees that they would switch their patients to Zoladex, given the profit that could be earned from the prescription of Zoladex. In an effort to stop LCA reimbursement and to encourage physicians not to switch their patients to Zoladex, TAP and its management undertook the following: TAP filed suit in United States District Court challenging LCA and TAP provided hundreds of free samples of Lupron to certain urologists in South Carolina as an inducement not to switch their patients to Zoladex while the litigation was pending. These free samples, like the free good "sold" to a doctor at a \$0 invoice price, were not a part of the quarterly sample allotment to sales representatives.

TAP's litigation to stop LCA in South Carolina ultimately failed. The Medicare carriers in seven other states implemented LCA by the end of 1997; and by the end of 1998, the carriers in seventeen other states implemented LCA. By the end of 2000, Medicare carriers in about 38 states had implemented LCA. Some of these carriers adopted an "LCA Grandfather Clause" which provided that for patients already on Lupron at the time of implementation of LCA, the carrier would continue to reimburse the doctor at the published AWP for Lupron and would apply LCA only for new patients. Given these grandfather clauses (which were applied in at least six states) and the differing start times for LCA in each state, determining the actual dollar impact

of LCA on reimbursements for a particular medical practice and across the board is very complicated.

At the same time that some Medicare carriers were implementing LCA to control Lupron reimbursements costs, health maintenance organizations were undertaking similar steps. Towards the end of the summer, 1996, an HMO in Massachusetts, Tufts Associated Health Plans (hereinafter "Tufts"), announced to urologists treating patients insured by Tufts who were suffering from prostate cancer that Tufts would, in general, only reimburse the urologist for the total cost of Zoladex.

LCA stopped or slowed the growth of Lupron reimbursements where implemented. The Chart below illustrates the experience of two states that did not implement LCA; as compared with the impact on reimbursements in South Carolina.

TABLE 6			
Year	South Carolina	Louisiana	Massachusetts
1994	\$3,617,773	\$6,363,156	\$6,825,149
1995	4,890,936	7,747,390	8,782,536
1996	7,046,286	9,281,755	11,573,918
1997	7,089,825	11,504,599	12,929,519
1998	8,442,907	12,700,105	13,920,810

Thus, in South Carolina, where LCA was implemented in May, 1997, reimbursements in that year by Medicare for GnRH agonists was

flat. In contrast, Louisiana, which did not implement LCA until January 1999, and Massachusetts saw steady growth in GnRH reimbursements in each year between 1994 and 1999.

E. Total Dollar Reimbursements for Lupron and Zoladex

The Medicare Program was just one of many insurers that, in the 1990s, paid for the prescription of Lupron and Zoladex. It was, however, the largest such insurer, paying for about 75% of all Lupron prescribed to men suffering from prostate cancer. The Government has ready access to Medicare Program payments; by contrast, the government does not have similar ready access to private insurance company payments for Lupron. Given that the vast majority of all patients receiving Lupron and Zoladex were insured by Medicare, the Government has used as a marker for calculating loss the billings to the Medicare Program.

In the 1990s, the Medicare Program paid, in the millions, for Lupron and Zoladex as follows:

TABLE 7			
Dollars in millions			
Year	Total Payments by Medicare	Medicare Payments for Lupron	Medicare Payments for Zoladex
1991	\$93.0	\$72.9	\$7.5
1992	191.6	160.0	18.4
1993	266.6	228.8	26.2

1994	342.6	295.2	36.4
1995	417.1	354.5	51.1
1996	529.1	453.8	66.1
1997	615.7	504.1	103.7
1998	667.4	457.7	203.8
Totals	\$3,123.1	\$2,527	\$513.2

As noted above, about 75% of all persons receiving Lupron as a treatment for prostate cancer are Medicare insured. These numbers reflect only Medicare payments for that 75% of all patients. If every doctor billed every Medicare patient the copayment - 20% of the doctor's bill to Medicare - and collected that amount from either the patient, or the patient's supplemental insurer, the total amount paid for Lupron and Zoladex for treatments to Medicare insured patients in each year listed in Table 7 would be increased by 25%. For example, \$504.1 million represents Medicare's payments to urologists for prescription of Lupron in 1997. That amount was 80% of the lesser of the billed amount or the published AWP; the total that the doctors should have collected from patients and all insurers in 1997 was \$630,000,000. Assuming that that number was 75% of the total "Lupron market" in 1997, the total Lupron reimbursements by patients and their insurers to all doctors was about \$840,000,000.

A small number of doctors received most Medicare Program



reimbursements for Lupron and Zoladex. In other words, most patients with prostate cancer were treated by a small percentage of all such doctors. For example, in 1997, a year in which Medicare spent \$504.1 million on Lupron, there were 14,316 urologists nationwide who submitted claims to Medicare for Lupron prescribed to patients. Of that number, 3.4%, or 482 urologists, received 25% of all monies paid out by Medicare for prescriptions for Lupron, or \$126 million. The top 25% of urologists (3,574) received 82%, or \$411.6 million, of the total \$504.1 million. Table 8 reflects this market power of the top doctors. The middle column states the total number of urologists that Medicare paid some money on claims for prescriptions of Lupron; the number of doctors in the last column—is the number of physicians who received fully 25% of all that Medicare paid out for Lupron in the indicated year. In short, the marketplace in which TAP sold Lupron was highly concentrated in a relatively small number of physicians.

TABLE 8		
Year	Number of Urologists	Number of Doctors In Top Quartile
1991	8,443	246
1992	11,212	331
1993	12,776	409
1994	13,905	454

1995	14,581	472
1996	14,703	475
1997	14,316	482
1998	13,032	432

While not all Lupron paid for by Medicare was billed to the Program by urologists, the vast majority was. Table 9 reflects for the indicated years the Medicare program payments for Lupron matched against the sales figures from TAP for sales to Urologists. TAP internally tracked sales to more than seventy classes of customers; the class of "urologists" in the years indicated as tracked by TAP did not include either oncologists, or sales to HMOs or hospitals.

TABLE 9			
Year	Medicare Payments for Lupron	Sales to Urologists	Urologists Sales as % of Total Sales
1993	\$228.8	\$235.6	60
1994	295.2	264.7	60
1995	354.5	343.0	62
1996	453.8	439.8	63
1997	504.1	442.9	62
1998	457.7	340.3	57

1. Sales to Particular Doctors

Table 10 reflects sales to selected physicians by year.

Where the doctor has not pled guilty, the Government uses in the

chart a letter in lieu of the doctor's name. The first number for each doctor is the total reimbursement from Medicare to the doctor for both Lupron and Zoladex: this is a marker for the value of the doctor's total business (at least his Medicare portion) to either TAP or the manufacturer of Zoladex. The second number is the percent reimbursed for Lupron as compared against the total reimbursement to the doctor for Lupron and Zoladex: the amount of the total business that TAP captured. Thus, in 1997, 100% of the amount paid to Dr. Zamstein was for Lupron. In 1998, the Lupron reimbursement from Medicare was only 26% of his total Medicare reimbursement: TAP lost, in that year, a substantial portion of his business.

Each of these four urologists received substantial numbers of free samples from TAP. Drs. Olstein and Zamstein have pled guilty to conspiring with TAP in the receipt and billing of free samples; Dr. Spinella has pled guilty to conspiring to accept kickbacks from TAP, in the form of free products, for the referral of Medicare insured business. By way of comparison, in some of the years listed below, Dr. X was the number one urologist nationwide in terms of total Medicare reimbursement received for Lupron.

TABLE 10				
Year	Jacob Zamstein	Joseph Spinella	Joel Olstein	Dr. X
1994	\$184,889 100%	\$80,474 99%	\$38,962 82%	\$652,350 100%
1995	\$242,492 100%	\$105,948 79%	\$124,969 86%	\$747,298 100%
1996	\$291,333 100%	\$168,128 99%	\$272,631 93%	\$1,015,064 100%
1997	\$398,162 100%	\$177,217 99%	\$346,999 59%	\$912,868 100%
1998	\$279,761 26%	\$165,153 28%	\$416,898 17%	\$746,862 100%

Dr. Spinella has pled guilty to receipt of free samples as a kickback to induce his continued purchases of Lupron. In the summer 1995, as he has admitted, he abruptly switched his business from Lupron to Zoladex. After a TAP sales employee gave to him 33 free one month samples in November and December 1995, Dr. Spinella switched his business back to TAP. As reflected in Table 10, in 1994, TAP had 100% of Spinella's business, worth \$80,000. In 1995, Spinella's Medicare business had grown to \$105,948, but TAP's share was only \$83,698 for the entire year. In 1996, after giving Spinella the free samples, TAP captured 99% -- \$166,446 -- of his business, which had increased overall to \$168,128.

For the same four urologists, Table 11 reflects the average reimbursement to the urologists for each one-month unit of Lupron or Zoladex in each of the years 1994-1998. The top number in each row is the average Lupron unit reimbursement and the bottom number is the Zoladex average unit reimbursement.

TABLE 11				
Average One-Month Dose Reimbursements for Lupron and Zoladex				
Year	Jacob Zamstein	Joseph Spinella	Joel Olstein	Dr. X
1994	362	367	356	363
	253	276	276	253
1995	382	379	376	372
	268	277	279	268
1996	401	400	397	394
	288	307	293	288
1997	410	414	411	394
	314	328	326	314
1998	397	400	416	329
	334	330	328	321

For example, in 1995 Medicare paid Dr. Spinella \$379 on average for each one month unit of Lupron that he prescribed. When he switched his patients to Zoladex, Medicare paid only \$277 to him for each one month injection. Accordingly, as a result of that switch, Medicare saved \$102 for each injection of a GnRH agonist to a Medicare Program beneficiary being treated by Spinella. In

total and including the difference in copayments, the beneficiaries saved \$127 on each monthly drug dose ( $\$379/0.8 - \$277/0.8$ ). In 1996, after Dr. Spinella had switched patients back to Lupron, Medicare paid Dr. Spinella \$376 on average for Lupron and \$279 on average for Zoladex. In that year, the switch back to Lupron cost Medicare \$93 more per dose on average and cost the patients, their supplemental insurers and Medicare in total \$117 more on average ( $\$400/0.8 - \$307/0.8$ ). The cost to patients for billings for the 33 free product given to Spinella in late 1995 to induce him to switch his patients was \$496.25 (the published AWP in 1996) times 33 = \$16,376.25. The cost to all patients from the switch by having to pay on average \$117 more in 1996 for monthly drug treatments; assuming no change in the number of patients, was \$117 times 12 months times 33 patients, or \$46,332 for one year alone.

What additional future losses were there? This number cannot be determined with precision and like many other aspects of determining loss in this case, is subject to a number of assumptions. Assuming:

no change in the number of patients in Dr. Spinella's practice through the end of 1997;

that he billed and collected 100% from all patients;

that every patient agreed to be switched back and forth from one drug to another; and

that the non-Medicare insured patients in his practice paid the same as the Medicare insured patients for both Lupron and Zoladex,

the cost to patients and all insurers in just two years from TAP's criminal conduct as to just Dr. Spinella was \$16,376.25 (the billings for the 15 free samples in 1995) + \$46,332 (for 1996 in extra billings for Lupron as opposed to Zoladex) + \$42,570 (for 1997 in extra billings) + \$6,947.50 (for the additional 1996 free samples) + \$3,093.58 (for the additional 1997 free samples) + \$14,056 (for the additional 1998 free samples) plus \$9,702 (for the additional cost to patients for the referral of 28% of his business in 1998) = \$139,076. This potential loss of \$139,076 was caused on business of Dr. Spinella that resulted in \$696,920 in total Medicare reimbursements to him. The loss number accordingly represents about 20% of the total payments by Medicare to Spinella for Lupron and Zoladex over a five year period.

Looked at another way, TAP provided to Dr. Spinella in 1995, 1996 and 1997 free drug worth \$33,530. That free drug also caused a loss, which, if all of the above assumptions are true, to the Medicare Program of about \$106,000 (\$139,076 - \$33,530) on Medicare program billings of about \$391,587 over the next three years. Thus, TAP provided samples worth (if billed) about 8.5% of the gross value of the business to Dr. Spinella and about 1/3

of the loss.<sup>2</sup>

Dr. Zamstein received between \$30,000 and \$40,000 in free samples from at least 1994 through 1997. In that time period, he received in reimbursement from Medicare for his billings for Lupron \$1,189,613.<sup>3</sup> Given that this figure was 80% of the charge to Medicare, the price charged the patient was \$1,487,016. In short, TAP gave Dr. Zamstein free product worth less than \$40,000 to insure a flow of business worth at least \$500,000 to TAP. Had Dr. Zamstein ordered Zoladex for his patients instead of the more expensive Lupron, the cost to the patients would have been only \$1,092,557, or \$394,459 cheaper.<sup>4</sup> This calculation

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<sup>2</sup>Each plea agreement with each physician has a cap in it for the amount that the Government may argue was the loss caused by the physician, which cap is below the total potential loss caused by the criminal conduct and closely correlates with the dollar value of the free samples provided to the physician. The Government agreed to these caps for one principal reason. At the time that the Government entered into the plea agreements with each of these physicians, the Government had not completed its analysis as set forth herein, and could not then estimate with accuracy all of the potential losses. The sophistication of the Government's analysis, and the ability to make that analysis with additional necessary information, has clearly improved during the course of the investigation, in part as a result of the extensive negotiations with TAP. At the time of sentencing of each of these physicians, the Government will assert a guideline range consistent with the information known to the Government at the time of execution of the plea agreements as agreed to in its plea agreements with each doctor.

$$^3184,889 + 242,492 + 291,333 + 398,162 + (.26 \times 279,761) = 1,189,613.$$

<sup>4</sup>This number is calculated as follows: For each year, the total reimbursement to Dr. Zamstein from Table 10 is divided by the average Lupron unit reimbursement figure in Table 11 to yield a number of units. That unit number is then multiplied by the



necessarily assumes that every patient Dr. Zamstein had on Lupron would have been on Zoladex, but for the provision to him of free samples.

A similarly complex and equally imprecise calculation can be performed for the loss caused by the provision of samples to each of the other doctors listed above. While one can use the estimates of loss from these doctors as a marker for the loss caused by provision of free samples to dozens of other physicians, it is a "rough" marker that provides only a general ballpark estimate of the probable loss caused by TAP's criminal conduct. While TAP's intent may have been the same from doctor to doctor - to provide the free product as an inducement for the doctor to order and prescribe Lupron - the doctor's intent may have differed, and, as the doctor's intent differed, the losses would as well.

F. Aggregate Loss or Gain Calculation

It is very difficult to calculate with any precision the total volume of free drug handed out by TAP to urologists in the 1990s; it is equally difficult to calculate the losses stemming from that conduct.

1. Losses stemming from billing for the free samples

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average Zoladex unit reimbursement figure for Dr. Zamstein in each year in Table 11. These yearly totals must then be added and divided by 0.8 to yield the total cost to the patient.

This number is difficult to calculate with precision across the broad array of TAP's conduct. On a doctor by doctor basis, as demonstrate above for Drs. Spinella and Zamstein, while the mathematical determination is straightforward and time consuming, it is wholly dependent upon a number of assumptions.

The government has not been able to determine with precision the total number of samples that TAP provided to urologists and others during the 1990s. In theory, sales representatives were supposed to have doctors sign for all free samples received -- and thus there is supposed to be a paper trail that reflects the samples given to each doctor. In reality the paper trail is incomplete and inaccurate. Some doctors refused to sign for samples; and sales representatives completed signature cards that showed the samples going to other doctors. Sometimes, the sales representative falsified the number on a card for one doctor to hide giving samples to another, or to hide the true number given to the first doctor. Sometimes doctors received free product without signature cards. Some representatives handed out more than 80 samples a year (one representative calling upon doctors in Connecticut documented handing out 135 samples in one year in the 1990s, almost double her allotment). Some representatives did not hand out all of their allotted samples. Some doctors have admitted to the Government receiving more samples than TAP's documents reflect. Other doctors have credibly denied receiving

any samples, notwithstanding that TAP documents reflect distribution of samples to those physicians. In addition to free "samples" TAP also provided urologists with free "product": injections of Lupron sent to TAP on invoice reflecting no charge. TAP tracked these free "products" differently than the free "samples" and there is no database that accurately reflects the total of such free drug.

a. The Practice Was Widespread

One factor that affects the magnitude of the estimated loss was the breadth of the illegal conduct among TAP employees: Did just a few representatives provide free drug with the expectation that the product would be billed or would induce doctors to prescribe the more expensive product, or was that practice widespread? Did the practice occur only in a short period or did it last throughout the 1990s? The evidence collected by the Government demonstrates that the practice was indeed quite widespread and of longstanding duration in the 1990s.

With between 190 and 250 sales representatives throughout the 1990s, TAP was dumping into the market in excess of \$7,000,000 in free drug every year. The provision of free drug to doctors to induce referrals was widespread and routine at the company. A short review of some of the anecdotal evidence will be of assistance to the Court in evaluating this conclusion by the Government. The Court should note that what is described

below is only a small fraction of the overall evidence that the government has that demonstrates that the practice of providing samples as an inducement to keep, gain or grow business was widespread.

A management employee who participated in the decision-making of the company regarding how to respond to the warning from the AUA doctor, observed, upon his transfer to California in 1994 widespread improper use of free product by sales representatives. In a memorandum to upper management in August, 1994, he wrote that "100% of the free goods used by Managed Care reps are used to effect a lower than invoice price." "The free goods used for pricing are sometimes used in addition to the quantity discount and can make the actual price for the customers less than our "best" price." "The potential for problems lies in the fact that these free goods are being offered contingent upon the purchase of a certain quantity of product." He then wrote:

One thing TAP can do ... is to stress to the ... sales reps that free goods should never be made available contingent upon a sale. Routine sampling of physicians can probably accomplish the same purpose without the potential risk. It could just be a coincidence that a customer receives a certain ratio of samples to purchased kits!

Another sales representative described to the Government that after the "formal" free goods for purchases program ended in 1994 or so, the representative was trained on the law that doctors were not supposed to bill for free samples, and,

paradoxically, she was given 20 plus samples per quarter to use "as she saw fit." On one occasion, her district was meeting and discussing problem accounts and Zoladex competition and what to do. Her manager told her that, to gain an advantage over the competition, she and her fellow representatives could provide to the doctors free kits to increase the doctor's return to practice profits; a minute later, he warned all of the representatives that, of course, billing for free kits was against the law. When that juxtaposition did not make any sense to the representative (encouraging her to give samples to doctors to increase their return to practice profits and telling her that billing samples was Medicare fraud) and that, if the doctor doesn't bill the samples, how did giving the samples to the doctor help him financially, the manager yelled at her and wanted to know why she just didn't "get it and what was so hard to understand about this." This representative also told the Government that she discussed with her fellow sales representatives at district, regional and national meetings, the quandary the company was putting them in: being told to provide free samples to doctors as an inducement to gain their business, in the context of a marketplace where the doctor would earn a profit from buying the drug (and hence it was logical to assume and believe that the doctor would take the free samples and bill them to his fee for service patients), all the while training the employees on the

law prohibiting billing for free samples.

Additionally, sales representatives have acknowledged that samples were provided to make up for lost discounts. Briefly, sales for bonus purposes were tracked by numbers of injections sold. Often it would occur that a sales representative would be close to hitting a sales target to earn a certain bonus level; if an account could be incited to buy early, then the rep would meet her numbers and earn the bonus cash, and perhaps also the award of a trip. In these circumstances, small numbers of free goods were sometimes used to induce purchases. One example: one representative asked a practice to order 116 units in December of one year rather than waiting until the following February, when they would normally order 150 units. While the account agreed, an employee of the account pointed out that by doing so, the practice would lose the 15% volume discount that they would have gotten in February by ordering the full 150 and that on the order of 116, the account would only get the 11 percent discount off list price. To make up this lost discount of 4%, the representative provided to the account, 3 free one-month kits to make up the difference between the 15-percent and 11 percent discount."

The only way for a gift of free goods to make up for the lost discount to an account was if the account billed for the goods. Thus this sales representative knew and understood, when

she offered the free goods, that the account would bill them.

b. Estimate of Loss from Billing Free Goods

As indicated above, TAP sales representatives provided to doctors somewhere between \$30,000,000 and \$60,000,000 worth of free product between 1993 and 1999. TAP also provided free drug on invoice to doctors and provided free drug in 1991 and 1992. The value of those latter categories of free drug is not clear, but likely exceeds an additional \$30,000,000. It is unclear how much of these amounts how were in fact billed to patients and their insurers. Many doctors investigated by the Government billed every free sample received; others billed none. If only half of the free product was billed to patients and their insurers at the published AWP, the loss to patients and insurers was between \$30,000,000 and \$45,000,000.

2. Losses Caused by Free Goods

A second loss arises from the doctor's prescription of the more expensive Lupron as a result of receipt of the free product as an inducement. Determining such losses with any precision is difficult and complex and, as demonstrated above for the analysis regarding Dr. Spinella and Zamstein, dependent upon reasonable assumptions. If the very rough 1/3 proportion seen in the Spinella example can be extrapolated across the entire population, that would predict a loss of between \$60,000,000 and \$90,000,000, assuming that half the free product was billed and

that that free product induced a doctor to prescribe Lupron and not Zoladex.

G. The Medicaid Rebate Program

The Medicaid Program is the nation's health care insurance program for the poor. The various State Medicaid Programs were, and throughout the 1990s were funded by both the federal government and the state in which the Medicaid program was operating.

Title 42 U.S.C. section 1396r-8 required that in order for a manufacturer of a drug to receive payment from the various State Medicaid programs for prescription of its drug to Medicaid program beneficiaries, the manufacturer had to enter into a rebate agreement with the Secretary of Health and Human Services. In such a rebate agreement, the manufacturer had to promise to sell its drug to the Medicaid programs at its best price. That section further defined best price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." The section also provided that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates" and did not include "prices that are merely nominal in amount."



On February 26, 1991, TAP entered into a Rebate Agreement with the Secretary of Health and Human Services. In that agreement, TAP agreed to comply with the section 1396r-8 and further agreed as follows:

1. TAP agreed to charge the Medicaid Program its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and make rebates where necessary.
2. TAP agreed that it would determine its best price based upon its average manufacturer's price, calculated as "Net Sales divided by numbers of unit sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid."
3. TAP agreed that prices in "bundled sales" would be included in determining its best price and that TAP would allocate the discount in a bundled sale "proportionately to the dollar value of the units of each drug sold under the bundled arrangement." TAP further agreed that bundled sales were sales involving the "packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."
4. TAP agreed that best price would not take into account nominal prices, defined as prices that are less than 10% of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

After execution of this agreement, TAP reported its average manufacturer's price in each quarter to the Medicaid Program, and reported in each quarter from 1991 through 2000, its best price

for a one month and three month doses of Lupron. From the first quarter of 1994 through the second quarter of 1997, TAP reported as its best price for Lupron 7.5 mg., \$298.53 and for Lupron 22.5 mg., \$895.59.

5. Non-Charged Best Price Violations

As the Court can see, one critical aspect of the civil settlement agreement is a repayment by TAP to all 50 state Medicaid Programs and the Medicaid Program in the District of Columbia for violations throughout the 1990s of TAP's obligation to report its best price to those programs and rebate them accordingly. TAP's net payments to the Medicaid programs and the Federal Government for those best price violations are in excess of \$50,000,000. That figure includes a multiple of the damages; single damage losses were estimated by the Government to be between \$15,000,000 and \$22,000,000.

While TAP is not charged in the instant criminal information with a best price violation, much of this loss was caused by providing doctor with free drug. Indeed, it is the position of the Government (not necessarily admitted to by TAP) that in some quarters in some fiscal years between 1991 and 1999, TAP's true best price to some customers was \$0. Urologists were given free drug in expectation that -- contingent upon -- their making future purchases of drug from TAP. Free drug provided to induce future purchases is free drug whose "purchase" price should have been

included by TAP in its reporting of best price to the Medicaid Programs. As one TAP employee admitted during the investigation, TAP never at any time throughout the 1990s included any free drug in calculating the best price that it was obligated to report to the Medicaid programs.

One example will illustrate this point. Dr. X, identified in Table 10, in the third quarter of 1996 obtained product from TAP at an average unit price of \$87.14, taking into account the free product he received and the product he purchased in that quarter. Nonetheless, in that quarter, TAP reported a best price of \$298.53 to the Medicaid Programs.

#### 6. Total Estimated Losses Caused by Free Goods

Adding these numbers together, the Government estimates that losses caused directly by TAP's giving of free samples to physicians to get and keep their business and given with the expectation that the doctors would bill those samples, falls somewhere between \$90,000,000 and \$135,000,000. Adding just half of the Medicaid best price losses, the losses caused by the free drug falls between 97,500,000 and \$146,000,000.

#### H. Losses Caused by the Provision of Other Inducements

As the Court is aware, a grand jury has charged TAP employees in a criminal indictment with conspiracy to provide inducements to physicians for the referral of Medicare and Medicaid insured business. That indictment specifies a

substantially broader conspiracy against those TAP employee defendants than is charged in this case as to TAP. In order to assist the Court in evaluating the sufficiency of the criminal fine as to TAP, a brief review here of that conduct is warranted.

As the Court can readily conclude from the parallel indictment, it is the position of the Government that TAP provided many other things of value, aside from free samples, to induce physicians to prescribe Lupron. These other inducements included money, called educational grants, discounts on other products for the referral of Lupron, employing doctors as consultants, providing them with trips to fancy resorts and providing them with free consulting services. These other inducements caused losses much like those caused by giving a doctor free samples: if the thing of value induced the doctor to prescribe Lupron as opposed to the cheaper alternative, the patient and his insurer was damaged by the difference in cost. While this broader conduct does not form the basis for the criminal charges in this case as to TAP, that conduct was used by the Government as a marker in determining an estimated gross loss of \$145,000,000 and is accordingly useful in evaluation of the fairness and adequacy of the proposed global criminal and civil resolution in this case.

It must be emphasized that calculating the total loss caused by any of these inducements is very difficult to accomplish with any precision. Set forth below are two types of such inducements

and an evaluation for the Court of the difficulties in measuring with precision the losses caused.

1. TAP Into the Future Programs

TAP provided to their best customers so-called "TAP into the Future" programs. These were all-expenses-paid weekends at fancy resorts. The budget for these events was usually about \$250,000, and attendance about 40 doctors, setting the cost of the weekend per doctor at about \$6,000. The trip included golf, skiing or white water rafting, depending on the location and the time of the year. The programs were called "consulting programs" and the doctors were referred to as "consultants." Over the course of 1995-1997, more than six such programs were held, with in excess of 200 urologists in attendance overall.

The doctors were in fact not typical consultants; indeed few of the normal trappings of "consultancy" existed: no consultant reports were prepared; the doctors never billed TAP for their time; the doctors were not hired on an hourly or other consulting basis (e.g., they were not paid a flat fee for preparing a report on a topic or giving a speech) either before or after the trip; and the sales employees who nominated the doctors to attend the "consulting" programs typically had no discussions with the doctors regarding the consulting services to be provided or that "had been provided" during the course of the weekend event.

One TAP employee, who helped to run these programs, has told the Government that the purpose of the program was to "invite people from accounts that were fence sitters or under pressure from Zoladex" "to get them to stop being a fence sitter" or "to get them to stay with TAP if they were under pressure from Zoladex." One goal was to get an account that was not using Lupron to start purchasing Lupron. One doctor who attended one such program on Captiva Island (which he has described as "the most luxurious thing" he had ever gone to), was told that only the best customers were invited as a thank you for the business. That doctor has testified that at the conference, there were presentations on how to make one's medical practice more lucrative and many informal discussions with TAP employees who were present on how to maximize the urologists' return to practice through the prescription of Lupron.

Another sales representative has told the Government that he offered one practice a trip to Aspen to keep the business. TAP's marketing department at times called these physicians consultants to TAP. Yet, the doctors in fact provided to consulting services to the TAP employees with whom they had frequent contact: the sales representatives. Sales representatives interviewed in the course of the investigation had denied knowing what consulting services the doctors who attended these events provided: they saw no bills, had no discussions before the trip regarding the

consulting services that the doctors would be providing to TAP, and they did not discuss with their managers what services they thought the doctors could provide when they nominated the doctors for the trip. Since the sales representative is the primary point of contact with the physician - he or she is often the only TAP employee who deals with the doctor on a regular basis, he or she nominates the physician to attend the event, he or she knows the physician's expertise if any, and he or she deals with the doctor on his return from the weekend of "consulting" to TAP - one would expect that, in the normal course of events, the sales representative would have some inkling what consulting services had been provided. That the sales representatives did in fact not have any idea regarding the consulting provided by the physicians to TAP supports the conclusion that in fact the physicians were not consultants and were merely receiving a benefit from TAP in their attendance at the event.

The United States is not hereby suggesting that every doctor who attended one of these events had criminal intent to accept a kickback or other inducement. Indeed, these events present a classic example of differing intents. It is the Government's belief that TAP and some of its employees clearly intended the events to induce some or all of the attending physicians either to switch to or to keep ordering Lupron. Assuredly, some, if not many, of the doctors who attended probably simply took advantage

of the free weekend, without being induced to order or to continue to order Lupron.

Showing "loss" from this conduct is accordingly quite complex. For those practices that were gained, or were maintained, one measure of the loss can be the cost to the Government from payment for the more expensive drug: had the doctor not been influenced by the weekend extravaganza, and had he switched his business to Zoladex, or kept his patients on Zoladex, the Medicare and Medicaid programs would have paid less for future treatments. Evaluating the number of such patients is similarly complex: given the difference in administration between Zoladex and Lupron, it is possible that some patients may have refused to switch from Lupron to Zoladex.

## 2. Educational Grants

Throughout the 1990s, TAP routinely gave doctors educational grants. Sometimes the grants had a specific educational purchase; on other occasions the grants were without strings attached. Like the free samples, grants were often offered by TAP employees to gain or keep business: to prevent the account from switching to the cheaper drug Zoladex. One example worth discussion here, as it pertains to the difficulty in determining with accuracy the loss caused by inducements, is the offer of educational grants to a doctor at Tufts Health Plan.

In this transaction, in the spring 1997, two TAP employees



offered a Tufts doctor with the power to effect a purchasing decision between Zoladex and Lupron \$65,000 in educational grants together with discounts on another product, in exchange for the switch from Zoladex to Lupron and in order to hide the true sales price to Tufts so that TAP would not have to report a lower best price to the Medicare Program. The TAP employees offered the Tufts doctor inducements in exchange for an exclusive lupron arrangement at Tufts, and specifically told the doctor that the inducements had to be off-contract and not reflected in the invoice price for the lupron 7.5 mg. The total off-invoice reduction in price that was offered to the Tufts doctor was about \$33,000 per month, or almost \$400,000 per year. In indicating why the discount had to be off invoice and would be reflected in the price of the other product and not the prostate cancer business, one of the TAP employees told the doctor that TAP "would love to be able to give you the discount on the prostate business but we have government pricing to protect."

Tufts, like many HMOs is not a closed panel HMO: doctors treating Tufts patients treat patients insured by other HMOs and by fee for service insurers, including Medicare. Tufts, however, is a large HMO in the New England marketplace. That affects doctors in this fashion: Many physicians who treat patients suffering from prostate cancer use in their practice either just Zoladex or just Lupron for reasons associated with convenience:

some doctors consider it easier to have just one product in the practice and prescribe just one product than to prescribe and track both for a number of different patients. If, for such a doctor, a significant insurer in that doctor's marketplace announces that the insurer will cover only Zoladex or only Lupron, such a physician would similarly determine to prescribe only the one drug for all patients. Tufts is such an insurer in the New England marketplace. Thus giving an inducement to Tufts to get it to not cover Zoladex and to switch back to Lupron has a market value and can cause a loss to Medicare and other insurers that is beyond the value and the cost to Tufts: other providers, affected by Tufts decision may also switch their patients from Zoladex to Lupron, thus causing other insurers to pay more for the treatment of their insured beneficiaries.<sup>5</sup>

Such losses are real but are very difficult to measure with precision. One doctor known to have switched from Lupron to Zoladex because of Tufts' initial decision received in 1996 from Medicare \$118,665 for prescribing Lupron and \$0 for Zoladex prescriptions. Tufts' switch to Zoladex was effective January 1, 1997; that physician switched all of his patients to Zoladex effective that month. His 1997 Medicare GnRH agonist receipts

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<sup>5</sup>That in fact happened here in reverse: some doctors who had been prescribing Lupron for all of their patients switched all of their patients to Zoladex because of Tufts announcement in the summer 1996 that it would no longer reimburse urologists for prescription of Lupron.

were \$114,329, of which 96% was for Zoladex; in 1998, Medicare paid him \$135,554 exclusively for Zoladex prescriptions. Thus, TAP lost, for just this one doctor in just two years more than \$245,000 in business. Had the bribery of the Tufts doctor been successful, it is likely this doctor, along with others, would have switched his business back to the more expensive Lupron.

#### I. Total Losses Caused by the Criminal Conduct

As the Court can see, the losses caused by TAP's criminal conduct regarding Lupron are real and substantial but cannot be determined with precision: at best the losses to Medicare and others can only be roughly estimated as the Government has done in this memorandum.

How accurate is this estimate? Throughout the 1990s, TAP focused its illegal activities, including provision of free drug, on those doctors and other customers capable of referring or influencing the referral of the most business: the "800 pound gorillas" in the marketplace, as one TAP executive called them in an internal document. One rough marker, therefore, of the loss caused by TAP is the value to TAP of the business from those top doctors. The numbers of these doctors, and sales to them throughout the 1990s, were as follows:

TABLE 12
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Year	# of Top Doctors	\$ Rec'd from Medicare (in millions)	Avg per Doctor
1991	246	\$8.6	\$75,609
1992	331	40.0	\$120,845
1993	409	57.2	\$139,853
1994	454	73.8	\$162,555
1995	472	88.6	\$187,711
1996	475	113.5	\$238,947
1997	482	126.0	\$261,410
1998	432	114.5	\$265,046

Had just one third of this very small percentage of doctors prescribed Zoladex instead of Lupron, monies paid by patients and their insurers for prescriptions of GnRH agonists would have been more than \$100,000,000 lower. Measured by this marker, the rough estimate of loss by the Government of between \$97,500,000 and \$146,000,000 seems appropriate.

Accordingly, given (1) the provision to the urology market place of tens of millions of dollars in free drug, much of which free product TAP expected the physicians to bill to patients and their insurers; (2) the secondary losses that TAP intended to cause patients and their insurers to incur by the physician's prescription of Lupron as opposed to the cheaper product, which secondary losses had to exceed the value of the free product provided by at least a substantial multiple, (g) the losses to the Medicaid programs caused by TAP's failure to include any free

product in reporting best prices to those programs; and (4) the broad array of other financial inducements TAP provided to customers to induce them to purchase and prescribe its more expensive product, Government has estimated the losses caused by TAP's criminal conduct at about \$145,000,000.

The Government acknowledges that this figure is not precise; nonetheless, the Government believes, after almost five years of investigation and two years of negotiations with TAP, that the figure fairly captures the losses caused by TAP's criminal conduct. And, in the context of the entire global settlement, a criminal fine of \$290,000,000 is fair and just. The global settlement forces TAP to repay to the state Medicaid Programs almost the entire amount spent by those programs for Lupron for program beneficiaries in the 1990s. In short, that aspect of the agreement means that the Medicaid programs will have obtained Lupron for their beneficiaries for eight full years for almost nothing. The \$528,094,800 civil settlement to the Medicare program represents about 15% of the full amount that Medicare spent on all Lupron in that same time period. In this context, a criminal fine of \$290,000,000, double the rough estimate of the gross loss suffered by patients and their insurers, seems fair, just and reasonable.

#### IV. Conclusion

The Government urges the Court to approve the severe

sentence and correspondingly the tough overall global settlement agreement. TAP's criminal conduct spanned nearly a decade. Its corporate criminal behavior, sanctioned at the very highest levels within the company, must be harshly punished. TAP engaged in its criminal activity in a decade which saw a marked enforcement of the health care criminal laws in other sectors of the health care industry, yet TAP continued to act with disdain and in utter defiance of the federal criminal laws. Indeed, one can aptly describe TAP's corporate culture as one that viewed the rules as things that applied, perhaps to others, but not to TAP. TAP and its management's view can be fairly characterized as follows:

Yes, sure there are rules, but, we operate in a tough competitive marketplace with other pharmaceutical companies. If our employees have to break some rules to win and beat the competition, well, that is what will happen. We have profits to earn and owners to keep happy and bonuses to earn for ourselves and obeying the rules will just have to take a number in line behind all those other priorities. So what if we are breaking the laws: so are our competitors: how can we be expected to follow the rules if they aren't?

TAP's defiance of the rules can be illustrated with two examples. First, in 1995, a neighboring corporation, Caremark, was prosecuted for providing inducements to physicians. That corporation settled with the Government and paid to the Government about \$30,000,000 in criminal fines and over

\$160,000,000 total. TAP's management was aware of that prosecution and even circulated among its employees a copy of a legal reporter discussing the prosecution and the punishment. Yet, TAP itself was then actively and aggressively engaged in crimes; the prosecution of its corporate neighbor had no effect whatsoever on TAP's conduct: general deterrence did not work as to TAP.

Second, also in 1995, TAP, in a moment of delicious irony, accused its competitor, the manufacturer of Zoladex, with providing inducements to physicians in violation of the Medicare fraud and abuse laws, to include the fact that employees of the competitor were giving free samples to doctors to encourage them to switch from Lupron to Zoladex. The competitor, in turn, accused TAP of the very same conduct. Top employees from the two companies met in a summit meeting to discuss this exchange of criminal allegations. Did the serious allegations curb TAP's conduct? Did TAP, aware of allegations that its employees had engaged in criminal conduct, undertake expeditiously to stop the behavior, to train its employees in the rules and to enforce their adherence to the rules? Did either company, in possession of information that a competitor was violating the rules, report the conduct to prosecutive authorities in an effort to clean up the industry? Unfortunately, the answer to all of these questions is no: TAP, cognizant of the rules and having been

accused of violations, simply carried on its business as it always had, full criminal speed ahead.

The punishment the Government proposes is harsh and severe and the attendant corporate compliance program will, hopefully, constitute a strong step to curbing future criminal conduct by TAP and others in its industry.

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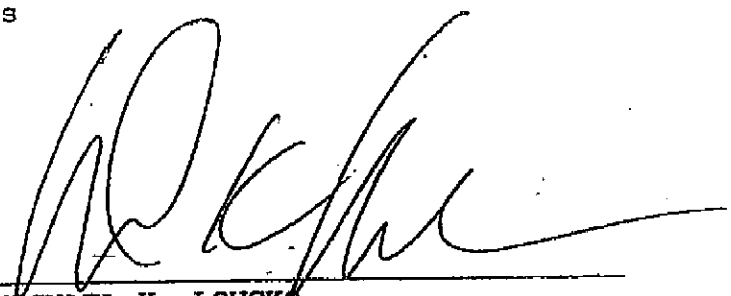


CERTIFICATE OF SERVICE

This is to certify that I have this day served upon the person listed below a copy of the foregoing document by depositing in the United States mail a copy of same in an envelope bearing sufficient postage for delivery:

Daniel Reidy, Esquire  
Jones Day Reavis & Pogue  
Chicago, Illinois

This 4th day of December.

  
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MICHAEL K. LOUCKS  
ASSISTANT UNITED STATES